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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,515	07/08/2003	Alex Gutteridge	674575-2004	9209

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,515	GUTTERIDGE ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *2-7,24-36,38-49 and 53-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-23,37 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of Group III, claims 1, 8-23, 37 and 50-52, in the reply filed on December 5, 2005 is acknowledged. Also acknowledged is Applicants' election of the species of inflammatory diseases in claim 52. Claims 2-7, 24-36, 38-49 and 53-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. No claims have been amended, canceled or added. Accordingly, claims 1, 8-23, 37 and 50-52 are examined on the merits herewith.

Regarding claim 3, this claim was mistakenly indicated as belonging in Groups I and III. This claim belongs in Group I only, because claim 3 recites a polypeptide that is a functional equivalent of SEQ ID NO: 2. As discussed previously, Group I is drawn to a polypeptide comprising SEQ ID NO: 2, while Group III is drawn to a polypeptide comprising SEQ ID NO: 6. Thus, claim 3 does not read on the elected group. Examiner apologizes for the error.

Applicants have traversed the restriction requirement, asserting that it is not a burden to search and examine all of the claimed inventions. Applicants also assert that the Commissioner may waive the restriction requirement and permit a reasonable number of nucleotide sequences to be examined together. In reply, Applicants have not presented their waiver from the Commissioner, nor have they elected a nucleic acid sequence as their invention for prosecution. Additionally, Applicants have claimed a vast number of inventions, both products and methods, in one application, as well as several protein

sequences and several nucleic acid sequences. As an illustration, each of claims 37, 50 and 52, in one claim, is drawn to six different products. As discussed in the previous Office action, it is most certainly a burden to search and examine multiple inventions, as each invention requires a different search and has different considerations with respect to each piece of prior art found in each search. For each protein or nucleic acid sequence, the results of searches in eight different databases must be considered. Each claim in each invention must also be examined for compliance with 35 USC §112- adequate written description, enablement and clear and definite claim language. Thus, Applicants' statements as to why all of their inventions should be examined together are not persuasive. Further, Applicants assert that the burden to Examiner of having to examine 48 different inventions is far less than the prejudice and burden placed on Applicants if a restriction requirement is maintained. But, prejudice and burden to Applicants are not criteria considered in the restriction of patentably distinct inventions, and Applicants have not explained what their prejudice and burden are. Filing claims to many different inventions together in one application, or in one claim, is elective on the part of Applicants.

Applicants have also asserted that Groups XXIV and XXVII should be examined along with the elected Group. In reply, as discussed in the previous Office action, should the elected product claims be found to be allowable, method claims commensurate in scope with the allowable product claims will be eligible for rejoinder under the Office's In re: Ochiai practice.

Applicants assert that their claimed as originally filed represent a web of knowledge and continuity of effort that merits examination together and that the previous Office action made no showing that the instant application meets the requirements for restriction. In

reply, web of knowledge and continuity of effort are also not criteria in restriction of different inventions. For any one protein molecule, it is likely that this molecule is related to other molecules and that it may be made and used in different ways. Thus, any protein molecule represents a web of knowledge and continuity of effort, as it may be the subject of ongoing research in multiple research labs, hospitals or medical clinics. The previous Office action explained in complete detail that each sequence is a patentably distinct invention and how each pair of inventions that was separated is a patently distinct invention. Thus, the previous Office action most definitely showed how and why each of the claimed inventions is patentably distinct and, as a result, why restriction is proper.

Regarding the species election, only claim 52 is relevant here, as the other claims in which a species election was required have been withdrawn. Applicants assert that, in the claims where multiple species are recited, there is a disclosed relationship among the species and that very few species are recited, so that there is no burden in searching and examining all of them. In reply, claim 52 recites a very large and disparate group of diseases (e.g., atherosclerosis and spinal cord injury), each with a different patient population, a different pathology, different causes and different treatments. Many species are recited (about 50). No relationship among the species is disclosed. Thus, it certainly is a burden to search and examine each species in this long list.

In view of the foregoing, the restriction requirement is maintained and is made final.

Priority

Applicants' claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicants have not complied with

one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119 as follows. Applicants claim foreign priority based on an application filed in Great Britain on January 11, 2001, but they not filed a certified copy of the British application as required by 35 U.S.C. 119(b). The specification must also be amended to include the priority claim as the first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite polypeptides that are a fragment of SEQ ID NO: 6 that has adhesion activity, an antigenic determinant of SEQ ID NO: 6, and a functional equivalent of SEQ ID NO: 6. No such fragments, antigenic determinants or functional equivalents are disclosed in the specification. Thus, one of skill in the art would have no idea which fragments, antigenic determinants or functional equivalents Applicants have in mind that they wish to include within the scope of the claimed invention. Also, one of skill in the art would have no idea which fragments of SEQ ID NO: 6 have adhesion activity, which portions of SEQ ID NO: 6 are antigenic determinants and what a functional equivalent of SEQ ID NO: 6 is.

Consequently, there is no evidence that any representative species of such large and varied genera- fragments with adhesion activity, antigenic determinants or functional equivalents- were in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because no fragments with adhesion activity, antigenic determinants or functional equivalents are disclosed, the claims fail to satisfy the written description requirement.

Claims 1, 8-23, 37 and 50-52 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide having the amino acid sequence of SEQ ID NO: 6, does not reasonably provide enablement for a polypeptide that is a fragment of SEQ ID NO: 6 with adhesion activity, an antigenic determinant of SEQ ID NO: 6 or a functional equivalent of SEQ ID NO: 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether or not undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice

the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary

skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1.Breadth of the claims.

The claims are very broad because they recite any fragment of SEQ ID NO: 6 with adhesion activity, any antigenic determinant of SEQ ID NO: 6 or any functional equivalent of SEQ ID NO: 6.

2. The nature of the invention.

The invention is designed to provide a novel protein that has adhesion activity.

3. The state of prior art.

Deutscher et al. ("Molecular analysis of the 60-kDa human Ro ribonucleoprotein, Proc Natl Acad Sci USA 85:9479-9483, 1988, see also the enclosed sequence alignment from searching the PIR database, Result 1) disclose the protein of SEQ ID NO: 6 (see Fig. 5, p. 9482). This protein was produced recombinantly in HeLa cells, extracts of these HeLa cells were prepared, and the protein was purified (see p. 9480, particularly left col., Ribonucleoprotein Reconstitution). Keene (US 5,541,291) discloses a protein having 64% sequence identity to SEQ ID NO: 6 (see bottom of cols. 15-16). Amino acids 28-372 of Keene's protein have 100% sequence identity to amino acids 194-538 of SEQ ID NO: 6 (see enclosed sequence alignment from searching the Geneseq database). Thus, Keene discloses a fragment of SEQ ID NO: 6 and a protein that is the human Ro autoantigen protein. O'Brien et al. ("*Xenopus* Ro ribonucleoproteins: members of an evolutionarily

conserved class of cytoplasmic ribonucleoproteins," Proc Natl Acad Sci USA 90:7250-7254, 1993) disclose the Ro ribonucleoprotein from *Xenopus laevis*, which has 81% sequence identity to SEQ ID NO: 6, the human Ro ribonucleoprotein (see p. 7252 and the enclosed sequence alignment from searching the PIR database- Result 2). Because both of these proteins are Ro ribonucleoproteins, and because these proteins are evolutionarily conserved (see title), it is likely that they have similar functions (see pp. 7250, 7253 and 7254).

4. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

5. The level of predictability in the art.

Because it is not known which fragments of SEQ ID NO: 6 have adhesion activity, or which portions are antigenic determinants, or which polypeptides are functional equivalents of SEQ ID NO: 6, apart from the one protein disclosed by O'Brien et al., the specification needs to have more detail as how to make and use the invention. Because the prior art and the instant specification do not disclose any fragments of SEQ ID NO: 6 having adhesion activity, or which portions are antigenic determinants, or which polypeptides are functional equivalents of SEQ ID NO: 6, apart from the one protein disclosed by O'Brien et al., it cannot be predicted that any fragments or portions of SEQ ID NO: 6 would retain these activities.

6. The amount of guidance present.

Applicants have not provided any guidance for preparing fragments of SEQ ID NO: 6 that have adhesion activity, or fragments that are antigenic determinants, or polypeptides are functional equivalents of SEQ ID NO: 6.

7. The existence of working examples.

The specification contains a data-mining working example that describes how SEQ ID NO: 6 was identified. There are no working examples related to fragments of SEQ ID NO: 6 that have adhesion activity, or fragments that are antigenic determinants or polypeptides are functional equivalents of SEQ ID NO: 6.

8. The quantity of experimentation necessary.

To prove that a protein comprising a fragment of SEQ ID NO: 6 has adhesion activity or is an antigen, or to prove that any protein performs the same function as SEQ ID NO: 6, many experiments would have to be conducted under a wide range of conditions. In these experiments, many different proteins that are many different fragments of SEQ ID NO: 6 would have to be prepared. Each fragment would have to have a different number of amino acids deleted, and for each number of amino acids deleted, the deletions would have to be in many different positions. Each of these many proteins would have to be tested for adhesion activity. Applicants have not provided an assay; consequently, an adhesion assay would have to be developed. A target molecule would have to be identified to which these proteins adhere, although, firstly, it would have to be determined to which molecules SEQ ID NO: 6 adheres, as Applicants have not provided this information. Adhesion would have to be tested for each protein under a wide range of conditions, e.g., buffers, temperatures, concentrations of the adhesion protein and the target protein. Additionally, for each of the many fragment proteins prepared, the degree to which each of these fragment proteins

elicits the formation of antibodies in a test animal would have to be determined. For each fragment protein, a number of different test animals would have to be tried, as the claims are not limited by species of animal. Regarding functional equivalents, all of the functions of SEQ ID NO: 6 would have to be determined, as Applicants have disclosed only one-adhesion. For each function, an assay would have to be developed. A vast number of very different molecules would then have to be tested, such as proteins, different types of organic polymers, and a large number of random organic molecules, to determine which of these have the same functional properties as SEQ ID NO: 6.

These types of experiments and data are missing from the specification. A great deal of guidance is needed to establish that a fragment of SEQ ID NO: 6 has adhesion activity or is an antigen or is a functional equivalent of SEQ ID NO: 6, because these polypeptides are claimed and no disclosure of such polypeptides is provided. Even if one such fragment or functional equivalent could be made or identified, by random, trial-and-error deletion or by identification in an assay, without a very large amount of data, such a result could not be expected with a different fragment or molecule under different assay conditions or in a different assay.

Therefore, the claims fail to satisfy the enablement requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 8-23 recite the term "functional

equivalent." This term is not defined in the specification. On p. 18, it is noted that functional equivalents may be polypeptides that are homologous to ADS5 or to the adhesion molecule regions of ADS5. But, the adhesion molecule regions are not indicated and homologous is also not defined. Applicants note only that homologous means "a high enough degree of identity or similarity." It cannot be determined what degree is high enough or in what way the functional equivalents are meant to be similar, i.e., what type of similarity is meant-structural, functional, a combination of the two, or something else. Thus, Applicants' meaning cannot be determined, and the metes and bounds of the claims are unclear. Appropriate correction is required.

Claims 8 and 9 recite the term "equivalent residues." This term is not defined in the specification. On p. 21, Applicants note that equivalent residues are those that are equivalent to the divalent metal ion binding residues, but it is not disclosed in what way amino acid residues should be equivalent to divalent metal ion binding residues. All that is disclosed is that serine is equivalent to threonine and that aspartate is equivalent to glutamate. Thus, it cannot be determined what Applicants intend to include in and exclude from the claims. Appropriate correction is required.

Claim 9 recites the term "BLAST." This term is a registered trademark. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. Thus, Applicants should amend the claim to indicate the legal status of BLAST by adding the ®.

Claim 21 recites the term "significant structural homology." The word "significant" is a relative term which renders the claim indefinite. This word is not defined by the claim, the

specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required. For example, Applicants may recite the desired degree of sequence identity or other definite structural features, such as particular amino acids at particular positions.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. The specification provides a background discussion of the families of adhesion proteins (see pp. 2-5) and lists a number of adhesion proteins (see pp. 6-9). The specification also notes that a portion of the protein of SEQ ID NO: 6 adopts an equivalent fold to that of a range of adhesion molecules and that three of the amino acids in SEQ ID NO: 6 are conserved among the adhesion molecule family as a whole (see p. 10, 3^{d} paragraph). But, the specification does not disclose the identity of SEQ ID NO: 6, that is, which protein this is, which target molecule it binds to (adheres to), which metabolic pathways this protein plays a role in, which diseases this protein is associated with, etc.

Thus, one of skill in the art would not know how to use the claimed invention. Consequently, it lacks a specific utility. Because the claimed invention lacks a specific utility, it lacks a well-established utility.

MPEP 2107.01.I.A (specific utility) provides guidelines for applying a rejection under this statute.

Part A: "A "specific utility" is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention. Office personnel should distinguish between situations where an applicant has disclosed a specific use for or application of the invention and situations where the applicant merely indicates that the invention may prove useful without identifying with specificity why it is considered useful. For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target."

Claims 1, 8-23, 37 and 50-52 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Deutscher et al. ("Molecular analysis of the 60-kDa human Ro ribonucleoprotein, Proc Natl Acad Sci USA 85:9479-9483, 1988, see also the enclosed sequence alignment from searching the PIR database, Result 1). Deutscher et al. disclose the protein of SEQ ID NO: 6 (see Fig. 5, p. 9482). This protein was produced recombinantly in HeLa cells, extracts of these HeLa cells were prepared, and the protein was purified (see p. 9480, particularly left col., Ribonucleoprotein Reconstitution). Thus, Deutscher et al. also disclose compositions comprising the protein of SEQ ID NO: 6. With regard to claims 37 and 50-52, these claims recite the intended uses of a composition comprising the protein of SEQ ID NO: 6. These intended uses do not materially change or affect the composition. As a result, the purified protein compositions of Deutscher et al. read on the compositions of these claims. A holding of anticipation is therefore required.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US 6,812,339, see also the enclosed sequence alignment from searching the issued patents database, Result 1). Venter et al. disclose the protein of SEQ ID NO: 6 (see Result 1, which discloses that SEQ ID NO: 6 has 100% sequence identity to amino acids 5-542 of Venter et al.'s SEQ ID NO: 10805). Compositions comprising this purified protein may also be prepared, by techniques that may be used with any recombinant protein (see col. 11, lines 40-50, and col. 12, lines 12-37). Thus, Venter et al.

also disclose compositions comprising the protein of SEQ ID NO: 6. With regard to claims 37 and 50-52, these claims recite the intended uses of a composition comprising the protein of SEQ ID NO: 6. These intended uses do not materially change or affect the composition. As a result, the purified protein compositions of Deutscher et al. read on the compositions of these claims. A holding of anticipation is therefore required.

Claims 1, 8-23, 37 and 50-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Burckhardt et al. (US 2003/0109901, see also the German equivalent, DE 19931380, to which the US application claims priority, and enclosed sequence alignment from searching the Geneseq database, Result 3). Burckhardt et al. disclose the protein of SEQ ID NO: 6 (see Result 3, which discloses that SEQ ID NO: 6 has 100% sequence identity to amino acids 13-550 of Burckhardt et al.'s SEQ ID NO: 1). Compositions comprising this purified protein may also be prepared (see paragraphs 20, 39-71, 76 and 77). Thus, Burckhardt et al. also disclose compositions comprising the protein of SEQ ID NO: 6. With regard to claims 37 and 50-52, these claims recite the intended uses of a composition comprising the protein of SEQ ID NO: 6. These intended uses do not materially change or affect the composition. As a result, the purified protein compositions of Deutscher et al. read on the compositions of these claims. A holding of anticipation is therefore required.

Claims 1, 9-16 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Brien et al. ("*Xenopus* Ro ribonucleoproteins: members of an evolutionarily conserved class of cytoplasmic ribonucleoproteins," Proc Natl Acad Sci USA 90:7250-7254, 1993, see

also the enclosed sequence alignment from searching the PIR database, Result 2). O'Brien et al. disclose the Ro ribonucleoprotein from *Xenopus laevis*, which has 81% sequence identity to SEQ ID NO: 6, the human Ro ribonucleoprotein (see p. 7252, Fig. 3, and the enclosed sequence alignment from searching the PIR database- Result 2). The protein of O'Brien et al. is a fragment of the claimed protein and contains the amino acids Ser378, Ser380 and Asp469. Because both of these proteins are Ro ribonucleoproteins, and because these proteins are evolutionarily conserved (see title), it is likely that they have similar functions (see pp. 7250, 7253 and 7254). Thus, the protein of O'Brien et al. may be considered a functional equivalent of the claimed protein. Therefore, a holding of anticipation is required.

Claims 1, 8, 11-14, 21-23, 37 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Keene (US 5,541,291, see also the enclosed sequence alignment from searching the Geneseq database, Result 8). Keene discloses the Ro (SS-A) protein, which has 64% sequence identity to SEQ ID NO: 6 and 100% sequence identity to amino acids 194-538 of SEQ ID NO: 6 (see cols. 15-16, Ro protein). Thus, Keene discloses a fragment of SEQ ID NO: 6 that contains the adhesion region of ADS5 (amino acids 373-503) and amino acids Ser378, Ser380 and Asp469 of SEQ ID NO: 6. Compositions comprising this fragment in purified form may be prepared (see col. 6, line 31, to col. 10, line 41; col. 10, lines 46-53; and col. 12, line 63, to col. 13, line 15). The protein of Keene is the Ro autoantigen protein (see Abstract; col. 3, line 58, to col. 4, line 21; and cols. 15-16, Ro protein). As an autoantigen, it comprises an antigenic determinant. Therefore, a holding of anticipation is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner, Art Unit 1653

rk/2006-01-20

Rosanne Kosson

ROBERT A. WAX
PRIMARY EXAMINER